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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/920,272	08/22/97	MILLER	F 08338/024003

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EXAMINER	
MURPHY, J	
ART UNIT	**PAPER NUMBER**
1646	21

DATE MAILED: 01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/920,272	MILLER ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,33,38,41-47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-33, 38, 41-47 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 31, 34-37, 39, 40 and 48 were cancelled, claims 32-33, 38, 41, 43-44, 46-47 were amended, and new claim 49 was added in Paper No. 20, 10/19/2000.

Claims 32-33, 38, 41-47 and 49 are under consideration.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

Response to Arguments and Amendment

The rejection of pending claims 32 and 43-45 under 35 USC § 102(b) as being anticipated by Schubert et al. (1985) has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of pending claims 32 and 43-45 under 35 USC § 102(b) as being anticipated by Ronnette et al. has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of pending claim 38 under 35 U.S.C. 102(b) as being anticipated by Schubert et al. (1985), in light of Fraichard et al. (1995) has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of pending claim 42 under 35 U.S.C. 103(a) as being anticipated by Schubert et al. (1985), in view of La Salle et al. (1993) has been obviated by Applicant's amendment and is thus withdrawn.

Claim Rejections - 35 USC § 112

Claims 46 and 47 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in Paper No. 18, 12/06/1999, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that based on the Wands factor analysis, the claims are enabled. However, as noted in the previous Office action, Applicant does not disclose the efficacy of such treatments in the relieving the pathophysiology of any disease state. The Declaration under 37 CFR 1.132 filed 06/06/2000 is insufficient to overcome the rejection of claims 46 and 47 based upon 35 USC 112, first paragraph as set forth in the last Office action. The Declaration demonstrates that a certain quantity of neural stem cells can be obtained from the peripheral tissue of a patient. There may indeed be a decreased chance for host rejection in the self-transplantation of these neural stem cells. However, it has still not been shown that the specification as filed teaches the skilled artisan the manner in which to treat a neurodegenerative disorder by transplantation of these neural stem cells. The specification does not adequately teach how to effectively treat any disease or reach any therapeutic endpoint in humans by administering neural stem cells. The specification does not teach how to extrapolate data obtained from the transplantation of the isolated precursor cells into the caudate-putamen complex of rat brain to the development of effective in vivo human therapeutic compositions, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of the neural stem cells exemplified in the specification.

Claim Rejections - 35 USC § 102

Pending claims 32 and 43-45 stand rejected, and new claim 49 is rejected, under 35 U.S.C. 102(a) as being anticipated by Sosnowski et al. (1995) for reasons of record set forth in Paper No. 18, 12/06/1999.

Applicant argues that i) Sosnowski did not include the step of isolating neural stem cells and ii) that Sosnowski only demonstrated the production of, inter alia, olfactory neurons. Sosnowski et al. states (page 46, first column, first paragraph) that '...cells were positive for the 200 and 160 kDa neurofilament protein, indicating they were neurons. A small number of these cells also labeled positive for OMP, a protein found in mature olfactory receptor neurons." (Emphasis added). Since only a small number of the cells identified as neurons were determined to be olfactory neurons, the non-OMP neurons were therefore not olfactory neurons. These cells transplanted in to the CNS, according to Sosnowski on page 47, second column, meet the limitations of claim 49, as well as 32, and 43-45. The recitation of a process limitation in claim 49 is not seen as further limiting the claimed product, as it is presumed that equivalent products can be obtained by multiple routes. The burden is on the applicant to establish a patentable distinction between the claimed and referenced antibodies/methods.
See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Claims 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Sosnowski et al. (1995), in light of Fraichard et al. (1995).

The disclosure of Sosnowski et al. has been set forth above. The Examiner has cited Fraichard et al. to show that it is an inherent property of neuroepithelial stem cells to express nestin (page 3183, column 2, second paragraph). Fraichard et al. (page 3185, column 1, second paragraph) discloses it is an inherent property of neurons to express enzymes involved in neurotransmitter metabolism, such as glutamic acid-decarboxylase. The disclosure of Schubert et al. therefore meets the limitations of claims 37 and 38. Se MPEP § 2131.01.

Claim Rejections - 35 USC § 103

P ending claim 33 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Mayo et al. (1992) in view of Kaufman et al. (1988), for reasons of record set forth in Paper No. 18, 12/06/1999.

Applicant has not addressed this rejection.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al (1995) in view of La Salle et al. (1993).

The disclosure of Sosnowski et al. has been set forth above. However, Sosnowski et al. does not disclose isolated precursor cells from olfactory epithelium transfected with a heterologous gene. The disclosure of La Salle (page 259, Figure 1) teaches the use of the adenovirus vector for the delivery of the beta-galactosidase gene. It would have been obvious to one skilled in the art at the time the invention was made to use the adenoviral vector for the transfection of the precursor cells isolated from olfactory epithelium with heterologous genes,

including trophic factors. The motivation is provided in the disclosure of La Salle (page 988, column 1, first paragraph), which teaches that the ability to deliver foreign genes and promoter elements directly to the nervous system would be desirable for the study of the function and regulation of cloned genes, as well as for gene therapy. Furthermore, La Salle (page 990, column 1, second paragraph) also teaches that in the context of degenerative diseases, it may be possible to express growth factors locally as an alternative to the grafting of fetal cells.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
December 29, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER